

between \$16.12 and \$36.11.

126. Aventis and Pharma also manufacture an injectable form of Anzemet®, prescribed for the prevention of chemotherapy related nausea and vomiting.

127. Congressman Pete Stark remarked on the manufacturers' untenable practices, noting that Hoechst had not created a spread for the tablet form of Anzemet® because tablets are dispensed through pharmacies and the Defendants must rely on regular marketplace competition to obtain market share in that forum.

128. Because Hoechst could control the AWP for the injectable form of Anzemet®, however, it could control clinicians' prescribing behavior without engaging in normal competition.

129. In a September 28, 2000 letter to the president of a national industry trade association, Congressman Peter Stark concluded that the drug companies have not lived-up to the responsibilities Congress allocated them in permitting them to formulate and promulgate "honest and truthful representations of their prices" as exemplified by the Hoechst's manipulation of Anzemet® Injectable AWP's. His letter included the following chart:

Price Representations for
Anzemet Injection

NDC NO:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1206-32	100 mg/5 ml Injectable	1	\$124.90	\$70.00	Represented price 78% higher than true wholesale price.

Anzemet Tablets

NDC NO:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1203-05	100 mg Tablets	5	\$275.00	\$289.75	Represented price 5% less than true wholesale price.

130. Hoescht thus falsely inflated the reported price of its Anzemet® to create an improper financial incentive and capture market share.

Effect of AWP Manipulation on Marketplace Competition

131. Competitors felt the effects of Defendants' fraudulent schemes. Glaxo Wellcome Inc. – makers of Zofran® a drug that competes directly with Anzemet® -- noted a decline in clinician use of its product due to availability of Anzemet® at a greater "spread" than Zofran®. Whereas, in a particular oncology clinic in Louisiana, the clinicians could procure Anzemet® for \$58.00 per 100 milligrams and receive a profit of \$84.29 from Medicare, procurement of 100 milligrams of Zofran® netted a mere \$69.60.

132. Defendants' marketing and sales documents, which were prepared and disseminated to their employees and agents via the US mail and facsimile over wire, compared the costs of the Covered Drugs to their competitors' costs and were intended to induce physicians to use the Covered Drugs and shift market share.

Defendant Baxter International's Manipulation of the AWP

133. Defendant Baxter has also engaged in an ongoing deliberate scheme to grossly exaggerate the AWP's for its Plan B pharmaceuticals.

134. The AWP for Baxter's product, Gammagard®, reflects a significant variation between prices paid by public consumers and Medicare Plan B recipients.

135. Baxter listed Gammagard®, or immune globulin, with an AWP of \$42.21.

136. In an independent study, the OIG estimated that the actual wholesale price for this drug fell between \$16.12 and \$32.11.

137. Baxter convinced clinicians to obtain and use its product by mailing or otherwise conveying through US mail and wires, notices of acquisition cost reductions and availability of free samples.

138. Further, the government's investigation revealed that Baxter intentionally increased the average wholesale prices for Covered Drugs with the specific goal of fraudulently increasing market share.

139. Baxter's internal documents indicate that manipulating the AWPs was, according to an internal memo, "a large part of [their] negotiations with the large homecare companies."

140. Baxter further admitted in internal documents that Homecare companies that reimburse based on AWP make a significantly higher margin.

141. Clearly, Baxter recognized that its conduct amounted to an invidious, institutionalized scheme to extort profit and market share through overcharging Medicare and Plan B participants.

142. Baxter prepared and disseminated documents to its employees and agents via the U.S. mail and wires to compare the costs of its Covered Drugs to its competitors' Covered Drugs with the intention of inducing clinicians to use Covered Drugs and shift market share.

143. Baxter's marketing pitches, as quoted by Representative Pete Stark, in a

September 28, 2000 letter to the president of a national pharmaceutical trade group, further demonstrate defendant's fraudulent practices:

BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price. . . free product given to achieve overall reduction."

Exhibit 8 to Representative Stark's letter is an internal Baxter memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution of free product to achieve overall price reduction.

144. An attachment to a letter by Chairman Committee on Commerce to Nancy-Ann Min DeParle Tom Bliley dated September 25, 2000, relates to Baxter and states:

The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers."

Defendant Bayer Corporations' AWP Manipulations

145. Defendant Bayer acknowledges its involvement in the AWP scheme in internal documents that attest to the fact that "many" health care providers are "paid on a discount from AW[P]."

146. Beginning in the early 1990s, Bayer began to falsely inflate reported drug prices. Bayer set an extremely high AWP and sold Plan B products to clinicians at a dramatic discount which enabled those clinicians to receive excessive reimbursement from Medicare and Plan B participants.

147. Bayer manufactures many Plan B pharmaceuticals which are widely used in treating hemophilia and immune deficiency diseases.

148. In an independent investigation, the DOJ concluded that Bayer's conduct in marketing the spread had the "effect of discouraging market competition from companies that do not inflate AWP's as a way of attracting doctors to their products."

149. The DOJ also found that "some physicians and home health companies ignore the products of companies that refuse to create these profit windfalls for customers."

Defendant Bristol-Myers Squibb Company's Manipulation of the AWP

150. In the 2000 edition of the *Red Book*, Defendant BMS listed the AWP for a 20 mg vial of injectable Vepesid® (Etoposide) as \$1,296.65.

151. BMS sold the exact same drug to a group purchasing organization for \$70 per 20 mg vial.

152. BMS had experience in manipulating prices with respect to Vepesid and recognized that its conduct interfered with physicians' medical decisions to use an alternative equal, Etopophos®.

153. BMS' own documents expressly acknowledged that the "Etopophos product profile is significantly superior to that of etoposide injection," but encouraged clinicians to prescribe etoposide injection based on the "growing disparity between Vepesid's list price and the actual acquisition price.

154. BMS also recognized that it could negate its competitors place in the marketplace "if the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished" even though it also recognized that this conduct resulted in great financial burden for Medicare and Plan B participants.

155. BMS's strategy of increasing the sales of its drugs by enriching, with taxpayer dollars, the physicians and others who administer drugs is reprehensible. It constitutes a

blatant abuse of the privileges that Bristol enjoys as a major pharmaceutical manufacturer in the United States.

156. BMS employed a number of other financial inducements to stimulate the sales of its drugs at the expense of the Medicare and Plan B beneficiaries that it illegally withheld from state and federal regulators. These inducements included volume discounts, rebates, off-invoice pricing and free goods designed to lower the net cost to the purchaser while concealing the actual cost of the drug from reimbursement officials, Plaintiffs and the Class.

157. BMS provided free injectable Etoposide® to two Miami, Florida oncologists, in exchange for their agreement to purchase other BMS cancer drugs. This arrangement had the effect of lowering the net cost of the cancer drugs to the oncologists and creating an even greater spread than would have resulted from the invoiced prices.

158. Free goods often provide substantial additional incentive to lure clinicians' participation into Defendant's scheme. The value of the free goods is often significant.

Defendant Chiron's AWP Manipulation

159. In its sale of Mitomycin® to clinicians over a four year period from 1995 to 1998 Chiron offered "spreads" from 15% to 155% to induce use of its product. None of the discounted saving illustrated by the chart below were enjoyed by Plaintiffs or other members of the class.

Chiron/Bedford

Mitomycin 20mg.
NDC#s 53905-0252-01
55390-0252-01

Year	“AWP”	New York Medicaid Reimbursement	True Cost	“Spread”	
				\$	%
1995	\$434.60	\$391.14	\$338.00	\$53.14	15.7%
1996	\$434.60	\$391.14	\$260.00	\$131.14	50.4%
1997	\$434.60	\$391.14	\$190.00	\$201.14	105.8%
1998	\$434.60	\$391.14	\$152.95	\$238.19	155.7%

Defendant Immunex Corporation’s AWP Manipulation

160. Immunex has not only participated in manipulating the AWP and extracting extra profit from Medicare Plan B participants, it has also deliberately attempted to hide its participation in the scheme by publicly insisting that pharmaceutical manufacturers have no control over the formulation or publication of the AWP.

161. In a letter dated September 28, 2000, to the president of a national pharmaceutical trade group, a member of the Congressional Ways and Means Committee exposed Immunex’s scheme, stating:

The documents further expose the fact that certain of your members deliberately concealed and misrepresented the source of AWP’s:

In a 1996 Barron’s article entitled “Hooked On Drugs,” the following quote from Immunex appeared (Composite Exhibit #11):

IMMUNEX: “But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren’t its own.” The drug manufacturers have no control over the AWP’s published . . .,” says spokesperson, Valerie Dowell. (IMNX003079)

162. However, Immunex’s own internal documents indisputably establish Immunex’s knowledge of the origin of their AWP’s and their active concealment:

LETTER FROM RED BOOK TO IMMUNEX:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system. The price changes that were effective January 3, 1996 were posted in our system on January 5, 1996. I have enclosed an updated copy of your Red Book listing for your files. If there is anything else I could help you with do not hesitate to call.

163. Immunex created and marketed this potential for profit to influence medical providers' decisions in prescribing Covered Drugs instead of competing drugs on the market and to benefit from an increased market share for the Covered Drugs.

164. Defendant Immunex gave clinicians further incentive to prescribe Covered Drugs by providing free samples and encouraging providers to providers to illegally bill Medicare for those samples, in clear violation of federal law.

165. The execution of this scheme of fraudulent incentives was an interstate endeavor intentionally carried out by the employees of Immunex.

Defendant GlaxoSmithKline's Manipulation of the AWP

166. GSK has engaged in an ongoing deliberate scheme to artificially and unjustifiably inflate AWP.

167. In 1996, GSK listed the AWP for its product Zofran® as \$5.65. In an independent investigation, the OIG discovered that the actual wholesale price for Zofran® for all consumers, *except* Medicare Part B participants, fell between \$4.33 and \$5.31.

168. In 1996, GSK also listed the AWP for its product Kytril® as \$165.29. The OIG discovered that the actual wholesale price for Kytril® for all consumers, *except* Medicare Part B participants, fell between \$123.58 and \$132.80.

169. GSK actively strategized to effectively respond to the negative

consequences of its illegal conduct by memorializing its concerns in a memo from its Pricing Committee:

If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. . . If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share. Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of government? How will this new pricing structure compare with costs in other countries? Is the [pharmaceutical] industry helping to moderate healthcare costs when it implements policies that increase the cost of pharmaceuticals to government?

170. GSK also expressed its concern over “the inflationary effect on government reimbursement of these pricing practices and the potential for an adverse counter-offensive” as well as a concern that the obviously vast difference between acquisition costs and the AWP it had listed might draw attention to its pricing practices, or worse, force HCFA to change the method of reimbursement for “all pharmaceutical and biological products.”

171. Congressman Stark has noted that “[p]erhaps the most striking example of the manufacturers’ recognition of the spread and the companies’ fraudulent abuse it represents is found in a revealing exchange of correspondence between corporate counsel from Glaxo and SmithKline Beecham in which each accuse the other’s company of Medicare fraud and abuse”:

GLAXO: “. . . In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their “profits” from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F) but charge Medicaid for three vials. this raises

significant fraud and abuse issues which I am sure you will want to investigate.”

SMITHKLINE: “In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate. . . The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third payors whose reimbursement is based on AWP. Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors.” (SB04277) (In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.)

172. Accordingly, Defendants recognized in each other illegal conduct even as each Defendant continued to engage in exactly the same manner.

173. Defendant Smithkline Beecham’s marketing and sales documents, which were prepared and disseminated to their employees and agents via the U.S. mail and facsimile over wire, compared the costs of the Covered Drugs to their competitors, and were intended to induce physicians to use the Covered Drugs and shift market share.

174. Defendant Glaxo’s price manipulation was no different, as evidenced in a letter from SmithKline. In an apparent effort to increase reimbursement to physicians and clinics, defendant Glaxo increased the AWP for Zofran by 8.5% while simultaneously fully discounting this increase to physicians.

175. The net effect of these adjustments was to increase the amount of reimbursements available to physicians from Medicare and other Third-Party Payors. Because the

net price clinicians pay Glaxo for the Zofran® the multi-dose vial is actually lower than Non Plan-B administration of Zofran®, it appears that the increase in the AWP was thus designed to increase overall sales per unit by Glaxo. This adjustment reflects Glaxo's intent to induce physicians to purchase Zofran® based on the opportunity to receive increased reimbursement from Medicare and other Third-Party Payors.

176. In an attachment, produced by Glaxo, to a letter of September 25, 2000 by Congressman Tom Bliley, it is evident that Glaxo expected negative reactions in choosing to increase the NWP and AWP for Zofran® in order to increase the amount of Medicare reimbursement for clinical oncology practices.

177. Glaxo expressed concern about how to explain raising the price for a drug "that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?"

178. Glaxo also expressed concerns that it risks "further charges that they are cost shifting to government in an attempt to retain market share."

179. Glaxo admits that private insurers, out-of-pocket payers, Medicare, Plan B recipients and third party payors are likely to incur greater costs as a result of this pricing strategy.

Defendants Pharmacia and P&U Manipulations of the AWP

180. The government's investigation revealed that Pharmacia and P&U have engaged in an ongoing deliberate scheme to inflate AWP's. For example, by letter dated May 25, 2000 to the HCFA administrator, the Chairman of the Commerce Committee revealed that:

[I]n 1998, Pharmacia-Upjohn's Bleomycin had an AWP of \$309.98, but health care providers could purchase it for \$154.85. In 1997, Pharmacia-Upjohn's Vincasar could be purchased for \$7.50, while the AWP was a staggering \$741.50.

(<http://comnotes.house.gov/cchear/hearings106.nsf/8eaabcee30ee07ee852566f900700fod/d2...>)

181. Pharmacia's marketing pitches, as quoted by Representative Peter Stark, in a September 28, 2000 letter to the president of a national pharmaceutical trade group, further demonstrate defendant's fraudulent practices:

PHARMACIA: "Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over \$8,000,000 profit when reimbursed at AWP. The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit."

Pharmacia thus proudly promoted a physician's ability to profit at the expense of Medicare and its beneficiaries.

182. Exhibit 1 to Representative Stark's September 28, 2000 letter demonstrates that, while the AWP for 1mg of Vincasar was \$370.75 in 1997, one physician's group (American Oncology Resources ("AOR")) 1997 price was actually \$4.15. Likewise, while the AWP for 2 mg of Vincasar was \$741.50, AOR's actual pre-April 1997 price was \$7.75 and Pharmacia had offered to reduce it to \$7.50. Accordingly, a beneficiary's co-pay amount alone was 560 percent more than the actual cost for the 1 mg dosage, and 506 percent more than the proposed reduced amount for the 2 mg dosage.

183. In a letter dated October 3, 2000 to Pharmacia, Representative Stark outlined numerous examples of illegal practices by Pharmacia to take advantage of Medicare and its beneficiaries as follows:

- a. The manipulated disparities between your company's reported AWP's and DP's are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of \$946.94 for 200 mg of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for \$168.00 and to Comprehensive Cancer Center for \$152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives.

Pharmacia and Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.

- b. Pharmacia and Upjohn's own internal documents...reveal that the company abused its position as a drug innovator in an initial *Phase III* FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit "2").

"...Clinical Research Trials

Initial Phase III Protocol trial for "oral Idamycin" in lymphomas. This trial will offer AOR \$1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at \$5,000 per patient...

The above...items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.

- c. It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from \$292.43 to \$309.98, while the price charged to industry insiders fell by \$43.15 (Composite Exhibit "4").
- d. Pharmacia & Upjohn reported price increases in October 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit "7" reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to \$152.00 while reporting an AWP of \$946.94:

"Dear Willie,

A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition..."

- e. Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia & Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including "educational grants" and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWP's and inflated reimbursements from the government. Composite Exhibit "8" highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL:

Medical Education Grants. A \$55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including Education/disease management, Research Task Force, AOR Annual Yearbook. A \$40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997...

PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO:

If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin...

Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin (emphasis added).

184. Likewise in an October 3, 1996 Pharmacia memorandum to thirteen oncology sales representatives, the sales representatives were told:

Our competitive intelligence tells us that our pricing on Adriamycin, although higher than generics, is in the "ball park" for you to attain the customers' Adriamycin business. If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin.

You should not have to use "free goods" to steer customer [sic] away from NSS or OTN. OTN and NSS Adriamycin pricing is competitive. Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to

direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin.

185. Moreover, included in the list of 479 drugs with inflated AWP's released by the Department of Justice to the States was Pharmacia's Adriamycin which had an AWP of \$241.36 as of April 2000, but an actual wholesale price of \$33.43.

186. Another example of, Defendant Pharmacia's use of inflated AWP's appears in a letter to an oncology clinic boasting of the savings offered off AWP.

Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers [the clinic] a reimbursement of over \$8,000,000 profit when reimbursed at AWP.

187. The attachment to a letter by Chairman Tom Bliley dated September 25, 2000 is shown below and indicates that Pharmacia had "spreads" of 33% to 80% (\$65 to \$124) from 1996 to 1998.

Pharmacia Bleomycin 15u NDC# 00013-1616-78						
Year	"AWP"	"Direct Price"	New York Reimbursement	True Cost	"Spread" %	\$
1996	\$292.43	\$233.94	\$263.19	\$198.00	\$65.19	33%
1997	\$292.43	\$233.94	\$263.19	\$175.00	\$88.19	50%
1998	\$309.98	\$247.98	\$278.98	\$158.00	\$120.98	76%
1998	\$309.98	\$247.98	\$278.98	\$154.85	\$124.13	80%

CLASS ACTION ALLEGATIONS

188. Plaintiffs bring this declaratory judgment and RICO action pursuant to Rule 23 of the Federal Rules of Civil Procedure, subsections 23(a) and 23(b)(2) and/or (b)(3), on behalf of a class defined as follows:

All persons and entities who paid any portion of the twenty percent (20%) co-payment or deductible amount for themselves or for their beneficiaries under Medicare Part B for Covered Drugs manufactured and/or distributed by Defendants during the period 1993 through the present (the "Class Period"). Excluded from the Class are all Defendants, their respective subsidiaries and affiliates, all

governmental entities, and all judges and justices assigned to hear any portion of this case.

189. The members of the Class are so numerous that joinder of all members is impracticable. Medicare beneficiaries number over 40 million nationally; 95% of Medicare beneficiaries elect to enroll in Plan B. Plaintiffs claims are typical of the claims of the Class Members. Defendants' unlawful conduct has been targeted against all members of the Class in a similar manner, *i.e.*, they have been subjected to unlawfully inflated stated reimbursement rates for drugs covered under Medicare Part B.

190. Plaintiffs will fairly and adequately protect the interests of the Class. The interests of the Plaintiffs coincide with, and are not antagonistic to those of, the Class. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action litigation, including the areas of mass tort, healthcare, consumer, and antitrust class actions.

191. Questions of law and fact common to the Class include, but are not limited to:

- (a) Whether Defendants engaged in a fraudulent scheme of improperly setting and/or adjusting the AWP for Covered Drugs;
- (b) Whether Defendants artificially inflated the AWP for Covered Drugs in order to increase their market share, sales figures, and revenues;
- (c) Whether Defendants prepared marketing and sales materials containing comparisons of the Red Book, Medi-Span, or Price Alert AWP for the Covered Drugs and the actual average wholesale price for these same drugs;
- (d) Whether Defendants actively sought to market "the spread" in order to induce clinicians to use Defendants drugs in lieu of other less-expensive and/or more effective drugs;
- (e) Whether Defendants engaged in a pattern and practice of selling Covered Drugs to clinicians at a price well-below the Red Book

listed AWP that the health care providers could recoup from Medicare (the “spread” price) so as to induce them to prescribe Covered Drugs to their patients;

- (f) Whether Defendants engaged in a pattern of racketeering activity as defined under RICO;
- (g) Whether Defendants participated in the operation and management of the association-in-fact conspiracy.
- (h) Whether Defendants received income derived from a pattern of racketeering activity and used or invested such income in the establishment and operation of the conspiracy;
- (i) Whether Defendants used or invested the income derived from a pattern of racketeering activity in the operation or management of the conspiracy;
- (j) Whether Plaintiffs and members of the Class were injured within the meaning of § 1964(c) of RICO as a direct and proximate result of Defendants’ investment or other use of illegally-obtained income into the conspiracy;
- (k) Whether the Defendants’ unlawful activities affected interstate commerce;
- (l) Whether Defendants engaged in a pattern of racketeering activity intended to defraud the Class;
- (m) Whether Plaintiffs and members of the Class were injured within the meaning of § 1964(c) of RICO, as a direct and proximate result of Defendants’ racketeering activities and predicate acts consisting of a wrongful scheme intended to defraud plaintiffs and the Class;
- (n) Whether Defendants’ fraudulent scheme was carried out and furthered by the use of the United States mail and interstate wire services; and
- (o) Whether Defendants are liable to plaintiffs and the Class for treble damages for conduct actionable under the civil provisions of the RICO statute; and
- (p) Whether injunctive relief is necessary to prohibit Defendants from engaging in unlawful conduct in the future.

192. The above-identified common questions predominate over individual questions, if any, that may affect the Class.

193. Class action treatment is a superior method for the fair and efficient adjudication of the controversy because it permits large numbers of similarly situated persons to prosecute common claims in a single forum simultaneously, efficiently, cost effectively in a manner that would be impossible if each individual filed separate actions. Furthermore, prosecution of separate actions by individual Class members would create an inherent risk of inconsistent and varying adjudications, with the concomitant risk of establishing incompatible and conflicting standards of conduct for Defendants.

**TOLLING OF APPLICABLE STATUTES OF LIMITATION
DUE TO FRAUDULENT CONCEALMENT**

194. The running of any statute of limitations has been tolled by reason of Defendants' knowing, active, and fraudulent concealment and denial of the fact as alleges herein. Defendants and their co-conspirators actively concealed their fraudulent scheme to inflate the prices charged for Covered Drugs by reporting AWP's that bore no relationship to the actual market cost of the Covered Drugs. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of the published AWP's.

195. Throughout the period of their unlawful conduct, each Defendant secretly engaged in activities unknown to Medicare beneficiaries to artificially elevate the price charged for Covered Drugs. Many, if not most, of those meetings, discussions and agreements took place, in whole or in part, in private. Plaintiffs and members of the Class were unaware of and could not through diligence have discovered these meetings or the true nature of Defendants' schemes.

**COUNT I
(Declaratory and Other Relief Pursuant to 28 U.S.C. § § 2201, 2002)**

196. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint.

197. An actual case and controversy exists between the Plaintiffs and each of the Defendants with respect to the Defendants' conduct of inflating the published reimbursement rates for drugs covered under Medicare Part B. The Plaintiffs contend that setting stated reimbursement prices above the actual average wholesale price for Covered Drugs is unlawful, and that each Defendant does so in violation of applicable law, knowing that Medicare beneficiaries and their insurers will incur similarly inflated substantial co-payments for drugs under Medicare Part B.

198. Each of the Defendants contends to the contrary. Each of the Defendants, either by itself or through groups or its trade association, contend that pharmaceutical manufacturers may exploit the Medicare reimbursement system without limit, and regardless of its affect on Medicare beneficiaries and their insurers.

199. The Plaintiffs, on behalf of themselves, their constituent members and all others similarly situated, are entitled to a judgment declaring that the practice of the Defendants of inflating stated reimbursement rates for drugs covered under Medicare Part B is unlawful, and are entitled to further relief pursuant to 28 U.S.C. § 2202.

COUNT II
(Violation of 18 U.S.C. § 1962(c))

200. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint.

201. Each of the Defendants is a "person" within the meaning of § 1961(3).

202. Millions of elderly and disabled Americans receive physician services and other health care under the Medicare program each year, including the provision of Covered Drugs under Medicare Part B. The Covered Drugs are prescribed and/or administered by

physicians, physician groups and other medical providers who both (i) seek reimbursement for the Covered Drugs through billings to carriers for the eighty percent (80%) federal share of coverage for such pharmaceuticals, and (ii) seek further reimbursement for the Covered Drugs through billings to Medicare beneficiaries and their insurers for the twenty percent (20%) private payor share.

203. Within the nomenclature of the RICO statute, each physician, physician group or medical provider unit is an “enterprise” within the meaning of 18 U.S.C. §§ 1961 (4) and 1962 (c). Each physician, physician group or medical provider unit, (each “enterprise,”) has a common and shared purpose that animates with those that become associated with the enterprise, *i.e.*, the provision of health services through the prescription and/or administration of Covered Drugs under Medicare Part B. Furthermore, each enterprise is a continuing unit within an ascertainable structure that is distinct from the wrongdoing alleged in this Complaint. The enterprise or enterprises at issue in this case are distinct continuing units, engaged in the provision of health care, who make available to America’s elderly and disabled population needed pharmaceutical products for serious medical conditions. Each enterprise was created and/or used as a tool to effectuate Defendants’ pattern of racketeering activity. The Defendant “persons” are distinct from each of these enterprises.

204. Alternatively, the “enterprise” at issue in this case may be viewed as the association-in-fact, within the meaning of 18 U.S.C. § 1961 (4), of all those persons associated together for the common purpose of selling, purchasing and providing Covered Drugs to Medicare beneficiaries under Part B of the Medicare Program. This enterprise consists of the various physicians, physician groups and other medical providers, along with other individuals and entities involved in the manufacture, marketing and distribution of Covered Drugs, as well as

the carriers for HCFA and HCFA itself. This Medicare Part B enterprise for Covered Drugs is, like the other enterprises described earlier, an ongoing and continuing organization of business consisting of both corporations and individuals associated for the common purposes of manufacturing, marketing, selling, purchasing, prescribing and administering Covered Drugs to Medicare beneficiaries.

205. Each of the enterprises described above engages in and affects interstate commerce because they engage in the following activities across state boundaries: the sale, purchase, prescription and/or administration of Covered Drugs, the receipt and/or transmission of sales and marketing literature, and the transmission and/or receipt of invoices and payments related to the use of Covered Drugs. Each enterprise or enterprises prescribes and/or administers Covered Drugs to Medicare beneficiaries throughout the United States.

206. Each of the Defendants is associated with the enterprise or certain enterprises described above.

207. In violation of 18 U.S.C. § 1962 (c), each of the Defendants has conducted or participated, directly or indirectly, in the conduct of the affairs of one or more of the enterprises described above through a pattern of racketeering activity. In effect, each Defendant has infiltrated the affairs of the enterprise or enterprises that prescribe and/or administer Covered Drugs under Medicare Part B manufactured by that Defendant through a pattern of racketeering activity, i.e., unlawful inflation of stated reimbursement rates for Covered Drugs. Among other things:

- (i) Each Defendant has directly controlled the price at which physicians and other medical providers purchase Covered Drugs;
- (ii) Each Defendant has directly controlled the published reimbursement rates

reported in industry publications;

(iii) Each Defendant has directly controlled the price at which physicians and other medical providers are reimbursed by Medicare beneficiaries and their insurers;

(iv) Each Defendant has directly controlled the creation and distribution of marketing, sales, and other materials used to inform physicians and other medical providers nationwide of the profit potential of Covered Drugs;

(v) Each Defendant has directly controlled the marketing and sales scheme to use the artificially and unlawfully inflated the Medicare reimbursement rate and co-payment rate to induce physicians and other medical providers to prescribe Covered Drugs to their patients;

(vi) Each Defendant has relied upon its employees and agents to promote the fraudulent marketing schemes through the mail, through the wires, and through direct contacts with physicians and other medical providers; and

(vii) Each Defendant has controlled and participated in the conspiracy with others in the marketing and/or distribution of its Covered Drugs by using a fraudulent scheme to manufacture, market and sell Covered Drugs through the use of unlawful inducements to physicians and other medical providers.

208. Defendants have conducted and participated in the affairs of the enterprise or enterprises through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. Defendants' pattern of racketeering likely involved hundreds, even thousands, of separate instances of use of the United States mail or the interstate wires in furtherance of their fraudulent and unlawful marketing scheme. Each of these fraudulent mailings and interstate wire transmissions separately constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively,

these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5) in which the Defendants intended to defraud plaintiffs and members of the Class.

209. Defendants' fraudulent and unlawful marketing schemes include (i) overstating the AWP for Covered Drugs, (ii) creating a "spread" based on the inflated figure to induce physicians and other medical providers to prescribe Covered Drugs to their patients; (iii) causing Medicare beneficiaries and their insurers to pay an artificially-inflated rate of reimbursement for Covered Drugs; (iv) providing free samples to doctors, and instructing them, with the intent, that they should bill Medicaid and the members of the Class for free samples; (v) providing other unlawful financial incentives to physicians to create greater demand for Covered Drugs; and (vi) actively concealing, and causing others to conceal, information about the true nature of the published AWP.

210. These schemes were calculated and intentionally crafted to ensure that Medicare and Medicare beneficiaries would overpay for Covered Drugs. In designing and implementing these fraudulent schemes, Defendants were at all times cognizant of the fact that the entire Medicare Program and all patients for whom Covered Drugs are prescribed, rely upon the accuracy of Defendants in setting the AWP as disseminated by the Defendants.

211. By intentionally and artificially inflating the AWP, and by subsequently failing to disclose such practices to the patients from whom reimbursement was sought through the United States mail or interstate wire transmission, each Defendant engaged in a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

212. These racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and members of the Class. Each separate instance of a racketeering activity perpetrated by each Defendant was related, had

similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the Class. Each Defendant has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the enterprise or enterprises.

213. Each Defendant's violations and pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Class to be injured in their property insofar as Plaintiffs and members of the Class have paid millions of dollars in inflated reimbursements or other payments for Covered Drugs.

214. Plaintiffs and members of the Class have relied to their detriment on billing statements based on information reported directly or indirectly by Defendants sent through the United States mail. As a result of Defendants' fraudulent acts, the billing statements so distributed have resulted in unjust overpayment from Plaintiffs and members of the Class.

COUNT III
(For Violation of 18 U.S.C. § 1962(d))

215. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this complaint.

216. Pursuant to 18 U.S.C. § 1962(d), "[i]t shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section."

217. Defendants violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c).

218. Each Defendant conspired with other persons and entities involved in manufacturing, marketing, distributing, selling, purchasing, prescribing and/or administering of Covered Drugs manufactured by that Defendant, and each Defendant agreed to derive, and

ultimately did derive, substantial income and proceeds from the above-described pattern of racketeering activity.

219. Each Defendant violated section 1962(d) by conspiring and agreeing to violate 18 U.S.C. § 1962(c). The object of the conspiracy and agreement by each Defendant was to conduct or participate in, directly or indirectly, the conduct of the affairs of each enterprise that was involved in the manufacture, marketing, distribution, sale, purchase, prescription and/or administration of Covered Drugs manufactured by that Defendant. Each Defendant's pattern of racketeering activity directly and proximately caused Plaintiffs and the Class to be injured in their business and property.

220. As a direct and proximate result of Defendants' direct and indirect acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § § 1962(c), Plaintiffs and members of the Class were injured in their business or property.

DEMAND FOR RELIEF

WHEREFORE, the Plaintiffs, on behalf of themselves and all others similarly situated, hereby demand that this Court enter the following relief:

1. That, under Count I of the First Amended Complaint, and pursuant to 28 U.S.C. §§ 2201 and 2202, the Court enter a judgment declaring that the practice of each Defendant of inflating the stated reimbursement rates for drugs covered under Medicare Part B is unlawful and fraudulent, and that the Court enter such additional declaratory and other relief as is appropriate under the circumstances so as to insure that lawful and accurate reimbursement rates are promulgated and used by each Defendant with respect to Covered Drugs under the Medicare Part B reimbursement and co-payment system;

2. Under Counts II and III, and pursuant to 18 U.S.C. §§ 1961, et. seq., this Court enter a judgment in favor of the Class and against each Defendant in an amount to

compensate the class for its injury to business and/or property suffered by reason of each Defendants' unlawful conduct;

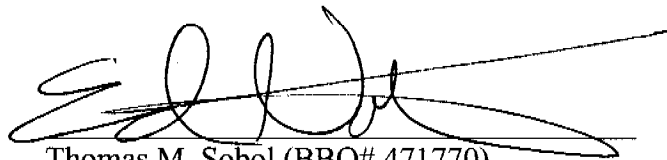
3. Under Counts II and III, this Court enter a judgment in favor of the Class and against each Defendant trebling the amount of damages suffered by the Class by reason of the unlawful conduct of each Defendant, plus an award of attorneys' fees and costs, and;

4. That the Court enter such other and further relief as is just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P 38 (b), the Plaintiffs demand a trial by jury on all issues so triable.

Date: March 18, 2002



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CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused a true and correct copy of the foregoing First Amended Complaint to be sent to the individuals on the attached Service List by hand or overnight delivery on March 18, 2002.

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